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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/899,432 | 07/06/2001 | Robert Kleiman | FLORA. 1100 | 3374 |

39602 7590 08/24/2006

NOBLITT & GILMORE, LLC.
4800 NORTH SCOTTSDALE ROAD
SUITE 6000
SCOTTSDALE, AZ 85251

| EXAMINER | |
|---|---|
| KANTAMNENI, SHOBHA | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/899,432 | KLEIMAN ET AL. | |
| | Examiner | Art Unit | |
| | Shobha Kantamneni | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *28 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *91-102* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *NONE* is/are allowed.

6)☒ Claim(s) *91-102* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's amendment filed on 4/24/2006, added new claims 91-102. Currently claims 91-102 are pending, and are examined on the merits herein.

Applicant's amendment by addition of new claims necessitated the new ground(s) of rejection presented in this Office action.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 91-102 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment submitted 4/24/2006 with respect to new claims have been fully considered but is deemed to insert new matter into the claims.

In the instant case, the specification as originally filed does not provide support for "wherein the antiviral activity of the composition is approximately 50 times greater than that of the alcohol component taken alone".

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 91-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392) in view of ARQUETTE et al. (WO 9920224).

Katz et al. (5,952,392) discloses that long chain fatty acids broadly including oleic acid (C18, one double bond, see col.2 lines 12-15; col. 3, lines 5-8, col.4, lines 26-28; col.6, lines 28-35) or monounsaturated long chain alcohols broadly (e.g., C18-C28, or octadecenol, docosenol, brassidyl alcohol) in their effective amounts with a physiologically compatible carrier (e.g., cream or ointment applied to skin, or aqueous solution, see col. 12, EXAMPLE 5; Examples 12, 14-15, col.20 lines 34-35, and col.22 lines 39-40 and 64) are useful in a pharmaceutical composition for topical application, intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity. See abstract, col.1 lines 10-15 and 20-47; col.3 lines 18-21; col.7, lines 62-67; col. 12, EXAMPLE 5; Examples 14-15 at col.22-23. It is further disclosed that compositions therein for use in treating viral infections comprise active ingredient or combination of compounds as the active ingredients selected from a group consisting of saturated aliphatic alcohols, mono-unsaturated aliphatic alcohols, mono-

unsaturated aliphatic amides and aliphatic acids having a carbon chain length of 18-28 carbons, wherein the active ingredient is present in an amount of 0.1 to about 50 % by weight of the final composition. See column 6, lines 28-36, lines 50-55. It is taught that the compositions therein are administered to the skin or a mucous membrane topically, parenterally or by transmembranal penetration using a cream, lotion, gel, ointment, suspension, aerosol spray or semi-solid formulation (e.g., a suppository). See column 7, lines 62-67; column 24, claims 7-11.

The prior art does not expressly disclose the employment of monounsaturated long chain alcohols in combination with long chain fatty acids salts, and fatty acid esters herein in a composition for treating virus-induced and inflammatory disease of skin and membranes.

Arquette et al. (WO 9920224) discloses a pharmaceutical composition comprising the instant fatty alcohols at least 10% by weight (see particularly abstract and page 3 lines 15-22), and the instant fatty acid esters in their various percentages (see page 4-8) with a physiologically compatible carrier for topical applications (see abstract and claims 1-12, claim 23). It is also taught that fatty acids such as oleic acid myristic acid etc are used as emollients in the pharmaceutical products. See page 1, lines 24-29.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the instant monounsaturated long chain alcohols in combination with the instant fatty acids herein in a pharmaceutical composition, in methods for treating virus-induced and inflammatory disease of skin and membranes.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the instant monounsaturated long chain alcohols in combination with the instantly claimed fatty acids herein in a pharmaceutical composition. Since all active composition components monounsaturated long chain alcohols, and fatty acids such as oleic acid are known to useful to treat virus-induced and inflammatory disease of skin and membranes according to Katz et al. (5,952,392), it is considered prima facie obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ the salts of fatty acid in the composition taught by Katz et al. (5,952,392). It has been well settled that pharmaceutically acceptable salts of the pharmaceutical compound are obvious over the pharmaceutical compound. Thus, the same fatty acids salts are deemed obvious over the same fatty acids taught by the cited prior art, having the same therapeutic effects and usefulness in treating virus-induced and inflammatory disease of skin and membranes.

It would have been obvious to a person of ordinary skill in the art at the time of invention to add instantly claimed fatty acid esters to the composition comprising monounsaturated long chain alcohols, and salt of fatty acids because Arquette et al. teaches that the instantly claimed fatty acid esters are known to be used as emollients in pharmaceutical compositions. Thus, one of ordinary skill in the art at the time of

invention would have been motivated to add the instantly claimed fatty acid esters to the composition comprising monounsaturated long chain alcohols, and salt of fatty acids with reasonable expectation of obtaining a pharmaceutical composition for treating virus-induced and inflammatory disease of skin and membranes since long chain fatty acids broadly or monounsaturated long chain alcohols broadly in their effective amounts with a physiologically compatible carrier are known to be useful in pharmaceutical compositions for topical application and intramuscular and intravenous injections, for methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes because these compounds have antiviral activity based on Katz et al.

Therefore, one of ordinary skill in the art would have reasonably expected that combining the instant fatty acid esters taught by Arquette et al. with the instant fatty alcohols, and the salts of instant fatty acid in a pharmaceutical composition would improve the therapeutic effect for treating virus-induced and inflammatory disease of skin and membranes because fatty acid esters are known to be used as an emollients in pharmaceutical composition, and emollients have beneficial effects such as softening, smoothening skin, reduce skin roughness, cracking and irritation of skin. Thus, one of ordinary skill in the art would have been reasonably expected that the combination of the instant fatty acid esters taught by Arquette et al. with the instant fatty alcohols, and the salts of instant fatty acid in a pharmaceutical composition would have at least additive therapeutic effects.

Claims 93-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katz et al. (5,952,392) in view of ARQUETTE et al. (WO 9920224) as applied to claims 91-92 above, and further in view of Katz (4,874,794) or Katz (5,070,107).

Katz et al., and ARQUETTE et al. are as discussed above.

Katz et al. (5,952,392) does not explicitly teach the effective amount of monounsaturated alcohol as from about 0.1 mg to about 2 gm per 50 kg of body weight.

Katz et al. (4,874,794) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C20-C26) with a physiologically compatible carrier in a pharmaceutical composition for topical application for methods of treating viral infections and skin inflammations are 0.1 to 25 percent by weight. See abstract, col.3 lines 63-68, claims 1-2.

Katz et al. (5,070,107) discloses that the effective amounts of long chain fatty alcohols broadly (e.g., C27-C32) with a physiologically compatible carrier in a pharmaceutical composition for topical application and intramuscular and intravenous injections for methods of treating viral infections and skin inflammations are 0.1 mg to 2 g/per 50kg of body weight. See abstract, col.3 lines 63-68, claims 1-2.

One of ordinary skill in the art would have been motivated to optimize the effective amounts of instantly claimed long chain monounsaturated alcohols in the composition because Katz et al. '794, and '107 teaches effective amounts of structurally similar long chain fatty alcohols active agents for treating viral infections and skin inflammations as 0.1 mg to 2 g/per 50kg of body weight. Further, it has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients,

in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Response to Applicant's Arguments:

Applicant's remarks filed on 4/24/2006 with respect to this rejection of made under 35 U.S.C. 103(a) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Further, Applicant's arguments that "nowhere does Katz et al. (US 5,952,392) disclose, teach or otherwise describe salts of fatty acids in combination with monounsaturated alcohols". This argument has been considered, but not found persuasive. As discussed above, the instantly claimed fatty acids, and monounsaturated alcohols are known to be useful in a pharmaceutical composition for topical application and intramuscular and intravenous injections, and methods of treating viral infections and virus-induced and inflammatory disease of skin and membranes. It has been well-settled that the non-toxic salts of the compound, i.e., the non-toxic salts of fatty acids to be employed in the same treatment as fatty acids, would be considered to be **obvious**, since one of ordinary skill in the art would recognize that the non-toxic salts of fatty acids and fatty acids would have same or substantially similar activities as anti-viral agents (see MPEP 2143.02).

***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
Art Unit : 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER